

**UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF VIRGINIA**

United States, et al.,
ex rel. **Mark Radcliffe,**

Plaintiffs,

vs.

Purdue Pharma, L.P., et al.,

Defendants.

No. 1:05CV00089

**MEMORANDUM IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS
RELATOR'S FOURTH AMENDED COMPLAINT WITH PREJUDICE**

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The Fourth Circuit recently clarified the reach of the False Claims Act in ways that are fatal to Radcliffe's case and require dismissal of his newest (Fourth Amended) Complaint. On November 5, 2008, the Fourth Circuit held that a six-year statute of limitations applies in False Claims Act cases where, as here, the government declines to intervene. *See United States ex rel. Sanders v. N. Am. Bus Indus., Inc.*, No. 07-1773, -- F.3d --, 2008 WL 4793577, at *4-*7 (4th Cir. Nov. 5, 2008). Significantly, the *Sanders* decision further requires relators to allege "FCA violations within the statutory period with the particularity required by Federal Rule of Civil Procedure 9(b)." *Id.* at *7 & n.3. Radcliffe's Complaint does not allege any specific violations within the limitations period or identify any particular allegedly false claims submitted to the government within the limitations period.

For these reasons, as well as a number of others discussed below, the Complaint should be dismissed with prejudice. After five attempts to properly allege an FCA case, Radcliffe should not be given a sixth. Were there facts sufficient to make out a claim for relief under the FCA, he should have alleged them by now.

I. THE COURT SHOULD DISMISS THE COMPLAINT BECAUSE RADCLIFFE ONCE AGAIN FAILS TO PLEAD FRAUD WITH PARTICULARITY

The Court dismissed Radcliffe's Third Amended Complaint because it "[did] not describe even a single instance in which a physician was influenced to prescribe OxyContin based on Purdue's misrepresentations, and where a claim for payment was made by the pharmacist to the government." September 30, 2008 Opinion ("Op.") at 42, as modified Oct. 14, 2008 [Dkt. 112, 120]. In False Claims Act cases, Rule 9(b) of the Federal Rules of Civil Procedure requires the relator to "provide details that identify *particular false claims* for payment that were submitted to the government." *United States ex rel. Rost v. Pfizer, Inc.*, 507 F.3d 720, 731 (1st Cir. 2007) (quoting *United States ex rel. Karvelas v. Melrose-Wakefield*

Hosp., 360 F.3d 220, 232 (1st Cir. 2004)) (emphasis added).^{1/} The Court recognized that Radcliffe had not done so. Op. at 42. He has again failed to do so. The requirement to identify “particular false claims” cannot be satisfied by adding a paragraph alleging four prescriptions written by a single doctor more than six years before Radcliffe filed his case, and a paragraph alleging a single marketing pitch to a hospital administrator that also occurred outside of the statutory limitations period and is unconnected to any particular prescriptions.^{2/}

A. The Complaint Does Not Allege Any Timely Violations with Rule 9(b) Particularity

The Fourth Circuit recently held that the FCA’s six-year statute of limitations applies in cases such as this, where the government declines to intervene. *See United States ex rel. Sanders v. North Am. Bus. Indus., Inc.*, No. 07-1773, -- F.3d --, 2008 WL 4793577, at *4-*7 (4th Cir. Nov. 5, 2008) (relator must comply with the six-year limitations period of 31 U.S.C. § 3731(b)(1)). Significantly, the Fourth Circuit held that a relator must allege “FCA violations within the statutory period with the particularity required by Federal Rule of Civil Procedure

^{1/} See also, e.g., *United States ex rel. Sikkenga v. Regence BlueCross BlueShield*, 472 F.3d 702 (10th Cir. 2006) (same); *United States ex rel. Clausen v. Lab. Corp. of Am., Inc.*, 290 F.3d 1301, 1311 (11th Cir. 2002) (“[I]f Rule 9(b) is to be adhered to, some indicia of reliability must be given in the complaint to support the allegation of *an actual false claim* for payment being made to the Government.” (emphasis in original)); *Sanderson v. HCA-The Healthcare Co.*, 447 F.3d 873, 878 (6th Cir. 2006) (“Rule 9(b) requires a *qui tam* plaintiff to do more than merely charge that the defendants engaged in fraudulent schemes that were pervasive and wide-ranging in scope and then argue[] that defendants must have submitted fraudulent claims to the government.”) (internal quotation marks omitted), *cert. denied*, 127 S. Ct. 303 (2006); *United States ex rel. Duxbury v. Ortho Biotech Prods., L.P.*, 551 F. Supp. 2d 100, 114 (D. Mass. 2008) (“[I]t is not enough to allege details of the scheme if there are not also particularized allegations regarding the false claims that were actually submitted to the federal government.”).

^{2/} The Fourth Amended Complaint is virtually identical to the Third Amended Complaint but for the addition of paragraphs 25-27, and 33. For the Court’s convenience, a redline comparison of the Third and Fourth Amended Complaints is attached as **Exhibit A**. Strikingly, Radcliffe once again refuses to specify which of the *seven* liability provisions of the False Claims Act, 31 U.S.C. § 3729(a), Purdue allegedly violated. *See* Compl. ¶ 35. This is inexcusable. The different provisions of § 3729(a) have materially different requirements and Purdue does not and cannot know which one(s) Radcliffe intends to pursue. To satisfy Rule 8(a)(2), a complaint must “give the defendant fair notice of what the . . . claim is and the grounds upon which it rests.” *Bell Atl. Corp. v. Twombly*, 127 S. Ct. 1955, 1964 (2007) (internal quotation marks and citations omitted). Purdue should not be required to answer such a complaint—or proceed to discovery—where Radcliffe himself has not even committed to the legal basis for liability. A well-pled complaint here would include meaningful counts that match Radcliffe’s several factual theories (e.g., misrepresentations to doctors, versus misrepresentations to particular federal officials, versus misrepresentations to particular state officials) to the statutory provision allegedly violated thereby.

9(b).” *Id.* at *7 & n.3. Radcliffe filed his original complaint on September 27, 2005. *See* Dkt. 3. Therefore, alleged violations that occurred prior to September 27, 1999 are time-barred—and, importantly, alleged violations after that date must be pleaded with Rule 9(b) particularity. Radcliffe has utterly failed to meet these requirements. To the contrary, he alleges misrepresentations made by Purdue from May 1996 to August 1999 and identifies only four “particular false claims” that were made in the summer and fall of 1998. Compl. ¶¶ 25, 26. Because these allegations fail to meet the pleading requirements articulated in *Sanders*, the entire Complaint must be dismissed.

1. The Alleged Misrepresentations to Physicians Are Time-Barred

In Radcliffe’s only allegation identifying any “particular false claims,” he alleges that in 1996, 1997, and 1998, he and a colleague made false marketing representations to Dr. Philip Jarvis in Rainelle, West Virginia, and that those representations induced Dr. Jarvis to prescribe OxyContin to four of his patients, whose prescriptions were ultimately paid for by West Virginia Medicaid in the summer and fall of 1998. Compl. ¶ 25. Every step of this sequence—from Purdue’s alleged misrepresentation, to the doctor’s prescription, to the ultimate payment of the claim by Medicaid—occurred before the six-year statute of limitations period that began in September 1999. The claims are thus time-barred, and Radcliffe is left without any factual basis for an FCA action based on alleged misrepresentations to private doctors.

Once the allegations in Paragraph 25 are stripped away under *Sanders*, Radcliffe is right back to where he was when the Court dismissed his Third Amended Complaint: without “even a single instance in which a physician was influenced to prescribe OxyContin based on Purdue’s misrepresentations, and where a claim for payment was made by the pharmacist to the government.” *Op.* at 42. Remarkably, Radcliffe addressed the very deficiency that doomed his previous complaint by adding allegations regarding only four prescriptions totaling less than

\$400—all from a single doctor, and all preceding the start of the six-year limitations period.^{3/}

The paucity of his amended allegations is telling—and fatal.^{4/} *See, e.g., United States ex rel.*

Foster v. Bristol-Myers Squibb Co., No. 9:05-CV-84-TH, -- F. Supp. 2d.--, 2008 WL 4360697, at *16-*17 (E.D. Tex. Sept. 24, 2008) (slip op.) (evaluating the sufficiency of the complaint based only on allegations within the statutory limitations period and dismissing it because they failed to satisfy Rule 9(b)); *cf. United States ex rel. Snapp, Inc. v. Ford Motor Co.*, 532 F.3d 496, 506 (6th 2008) (affirming dismissal because the relator did not “identify any individual representative claim for payment made by [the defendant] to the federal government during [the relevant] time period”).

Without any actual false claims that could form a basis for relief, Radcliffe’s case must be dismissed. In similar circumstances involving alleged prescription drug fraud, courts have repeatedly dismissed cases that attempt to recover for large pools of allegedly fraudulent prescriptions where the relators fail to allege specific examples of actual claims that were fraudulently submitted to the government. Most recently, in *Foster*, the court dismissed a case against Bristol-Myers Squibb (BMS) alleging that it had provided illegal kickbacks to doctors to induce them to recommend a BMS drug over that of a competitor. The relator alleged that “[a]ll

^{3/} The six-year statute of limitations in 31 U.S.C. § 3731(b)(1) could not have been a surprise to Radcliffe, as Purdue briefed the issue in its motion to dismiss his Third Amended Complaint. *See* Mot. to Dismiss Third Am. Compl., 31-32 [Dkt. 44]; Reply in Support of Mot. to Dismiss, 29-32 [Dkt. 61]. Even though there was some dispute in the case law at the time, the Fourth Circuit in *Sanders* merely adopted the already prevailing view. *See Sanders*, 2008 WL 4793577, at *6-*7 (“Our interpretation of Section 3731(b) is decidedly the majority approach in the federal courts of appeals, where no circuit court has accepted [the relator’s contrary] view [citing circuit cases]. . . . The majority of district courts in circuits other than these are also in accord with our interpretation.”).

^{4/} Radcliffe’s failure to allege examples within the statutory limitations period also highlights the incoherence of any theory of liability that would have a doctor fraudulently misled by marketing claims regarding relative potency even after several years of personal experience prescribing the drug. Such a physician would know whether OxyContin was twice as potent as morphine from his or her own prescribing experience, and this knowledge would inform each of the physician’s subsequent prescribing decisions. Thus, it is hard to understand how an alleged false claim as to relative potency could influence any prescription beyond at most the first few.

claims for payment resulting from these illegally-induced recommendations were false claims.” 2008 WL 4360697, at *18 (quoting complaint). The district court held that the complaint failed to satisfy Rule 9(b) because the relator did “not list one instance in which a[] . . . doctor selected a BMS drug over that of a competitor” and noted that the complaint did “not even provide general statistical information to indicate the frequency with which . . . doctors prescribe BMS drugs.” *Id.* at *17. Earlier this year, in *United States ex rel. Duxbury v. Ortho Biotech Prods., L.P.*, 551 F. Supp. 2d 100 (D. Mass. 2008), the court dismissed a case by a former sales representative against a pharmaceutical manufacturer that had allegedly provided kickbacks to doctors to induce them to prescribe one of its drugs, allegedly resulting in false claims to Medicare. *Id.* at 114. The court dismissed the kickback claims because the relator “fail[ed] to identify a single false claim consequently filed by these providers.” *Id.* at 115. Similarly, in *Rost*, the First Circuit affirmed the dismissal of a case alleging that Pfizer had provided kickbacks to induce doctors to prescribe one of its drugs for off-label uses. 507 F.3d at 734. Like Radcliffe, the relator in *Rost* alleged that “[t]he false claims were presented by thousands of separate entities, across the United States, and over many years.” *Id.* at 726 (quoting complaint); *compare* Compl. ¶¶ 38-39. The First Circuit concluded that the complaint failed to satisfy Rule 9(b). *Rost*, 507 F.3d at 733.

The same pleading deficiencies that required dismissal in *Foster*, *Duxbury*, and *Rost* also require dismissal here.^{5/} Like each of those cases, Radcliffe’s case is an attempt to recover for

^{5/} Indeed, in *Duxbury*, the court specifically rejected the legal argument that Radcliffe makes in Paragraph 38 of his Complaint. The relator there argued that he could not “identify all the false claims submitted to the government because the claims ‘were submitted by Providers with most of whom Relator has had no dealings, and the records of the false claims are not within Relator’s control.’” 551 F. Supp. 2d at 116 (quoting complaint). The court squarely rejected the notion that this excused compliance with his pleading obligations: “[T]his is precisely the point of requiring relators to identify particular claims, for under *Karvelas* and *Rost* the court is not permitted to surmise that false claims ‘must have’ occurred as a result of defendant’s conduct. No matter how likely the existence of false claims, this court cannot speculate that such claims inevitably flowed from Defendant’s activities.” *Id.* (citations and internal quotation marks omitted).

federal payments covering massive pools of prescriptions that were alleged to have been fraudulently induced by pharmaceutical marketing practices. And as in each of those cases, Radcliffe has not alleged any actual false claims that would entitle him to relief. As the Court recognized in dismissing Radcliffe's Third Amended Complaint, an FCA case cannot proceed under these circumstances. Because Radcliffe has failed to cure this defect, his Complaint must once again be dismissed.

2. The Alleged Misrepresentations to Government Officials Are Time-Barred and Are Not Pled With Rule 9(b) Particularity

The "circumstances required to be pled with particularity under Rule 9(b) are the time, place, and contents of the false representations, as well as the identity of the person making the misrepresentation and what he obtained thereby." *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 784 (4th Cir. 1999) (internal quotation marks omitted). None of Radcliffe's allegations regarding Purdue's representations to the government meet this standard. Nor does he identify any "particular false claims," *i.e.*, prescriptions, stemming from them. Nor does he meet the *Sanders* requirement that the relator allege violations within the limitations period. *See* 2008 WL 4793577, at *4-*7. Accordingly, Radcliffe has failed to adequately plead the elements of an FCA violation.

The Complaint alleges that on August 9, 1999—six weeks prior to the start of the statutory limitations period—Radcliffe and a colleague made a sales call to the pharmacy director at the VA Medical Center in Salem, Virginia, during which they made an allegedly false marketing representation about the 2:1 potency ratio. Compl. ¶ 26. The Complaint further alleges that "at that meeting"—*i.e.*, still prior to the start of the limitations period—the pharmacy director "commit[ted] . . . to allow the expanded use of OxyContin by Salem VAMC." *Id.*

Radcliffe then summarily sets out the Salem VAMC's total purchases of OxyContin from the following May, June, and July—nearly a year after the sales pitch. *Id.* But Radcliffe does not allege that the pharmacy director ever took action on his “commitment” or, if he did so, what he did or when he did it or how that action influenced the doctors making the prescribing decisions. Radcliffe identifies no prescriptions or “particular false claims” from the Salem VAMC that were allegedly induced by the marketing pitch or resulted from the “commitment.”

The allegations in Paragraph 26 do not satisfy Rule 9(b) for two reasons. First, Radcliffe does not identify any “particular false claims” that were submitted to the government as a result of the alleged misrepresentation. He does not identify a single prescription written or paid because of his conversation with the pharmacy director. Second, he provides no allegations that even suggest how his conversation with the pharmacy director could have caused prescriptions to be written or paid. There are no allegations that the pharmacy director ever spoke with a single doctor in order to tell such a doctor anything about the relative costs or potencies of OxyContin and MS Contin. Even if the pharmacy director had done so, of course, the doctor may have prescribed OxyContin for other reasons. Radcliffe merely alleges that each VA hospital had a local official in charge of that hospital's list of approved drugs and who “therefore determined whether a physician practicing at that hospital could prescribe OxyContin” (Compl. ¶ 23). But this merely means that a pharmacy director might be able to bar the use of OxyContin if he wanted to—it says nothing at all about the cause of any prescription, and thus the cause of any “claim” to the government for payment. Further, Radcliffe does not allege that prior to the alleged misrepresentation OxyContin was not on the Salem VAMC formulary list and after the misrepresentation it was added to the formulary, or that guidelines for its use were altered after the alleged misrepresentation was made. At bottom, Paragraph 26 provides no specificity

regarding claims that actually resulted from the alleged misrepresentation, nor any specificity about any actions at all stemming from the alleged misrepresentation. The allegations regarding Purdue's representations to the Salem VAMC thus fail under the Rule 9(b) standard the Fourth Circuit articulated in *Harrison*. See 176 F.3d at 784 (requiring the relator to allege, among other things, "what [was] obtained" by the defendant's fraud).

The only other new allegation in the Complaint is that Purdue managed care representatives, including Mike Heizman, made misrepresentations to (unidentified) state Medicaid officials in order to get OxyContin on state Medicaid formulary lists. See Compl. ¶ 27. This allegation could hardly be more vague, general, and lacking in specificity, and it plainly fails to satisfy the Rule 9(b) requirements of both *Sanders* and *Harrison*. First, Radcliffe does not allege a single date on which Heizman or any of his unnamed colleagues made the representations to state officials; whether the representations occurred within the limitations period is thus a matter of pure speculation. The allegation therefore fails to satisfy *Sanders*. See 2008 WL 4793577, at *7 & n.3 (requiring allegations of "FCA violations within the statutory period with the particularity required by [Rule] 9(b)"). Second, even if the representations had occurred within the limitations period, the allegation is nonetheless insufficient under Rule 9(b) because it includes neither the names of any of Mr. Heizman's colleagues, the dates or places of these unnamed representatives' representations to state officials, the contents of those representations, the manner in which they were made, what was obtained thereby, nor any particular false claims to the government resulting therefrom. See *Harrison*, 176 F.3d at 784, 789.

B. Even if the “Claims” that Radcliffe Alleges Were Timely or Pled with Particularity, They Would Not Support Recovery for Every OxyContin Prescription Paid for by the Government from 1996 to 2005

Assuming Radcliffe had identified at least one “particular false claim” within the statutory time limit—and he did not—his Complaint would still be deficient for failing to “[plead] with specificity . . . characteristic examples that are illustrative of the class of all claims covered by the fraudulent scheme.” *Snapp*, 532 F.3d at 508 (internal quotation marks omitted). More precisely, the relator must allege specific examples that are similar “in all material respects, including general time frame, substantive content, and relation to the allegedly fraudulent scheme . . . such that a materially similar set of claims could have been produced with a reasonable probability by a random draw from the total pool of all claims.” *Id.* at 508 (quoting *United States ex rel. Bledsoe v. Community Health Sys., Inc.*, 501 F.3d 493, 510-11 (6th Cir. 2007)). Radcliffe has not done so.

The examples Radcliffe provides fail to meet this standard because “the total pool of all claims” for which Radcliffe seeks recovery is not at all homogenous. According to the Complaint, only *some* OxyContin prescriptions from only *some* doctors were affected by alleged misrepresentations, while others were prescribed by doctors who were not influenced by the 2:1 potency representation (or, presumably, others who never learned of it) and thus prescribed OxyContin for other reasons. *See* Compl. ¶ 16 (“[Dr. Daniels] never accepted the 2:1 claim and prescribed OxyContin only for patients who could not tolerate MS Contin or other less expensive medications.”); *see also id.* ¶¶ 17, 19 (describing other doctors who also were not influenced by the 2:1 claim). Radcliffe is thus required to identify specific claims for which he seeks recovery; he cannot ask the Court to simply infer that they occurred. *See Snapp*, 532 F.3d at 508; *cf. Rost*, 507 F.3d at 732-33 (declining to infer that claims had been submitted where it was a “possible[,] but not a necessary or even strong inference” that the defendant’s inducements to doctors

resulted in any prescriptions to federally insured patients); *Duxbury*, 551 F. Supp. 2d at 114-15 (dismissing case where no specific claims were alleged and noting that “it is not enough to allege details of the scheme if there are not also particularized allegations regarding the false claims that were actually submitted to the federal government”); *Foster*, 2008 WL 4360697, at *17-*18 (similar). He has not done so.

The only claims Radcliffe specifically identifies are those submitted in connection with the four prescriptions that one single doctor, Dr. Jarvis, wrote in 1998. Compl. ¶ 25. But Radcliffe concedes that claims associated with prescriptions by other doctors—*i.e.*, Dr. Daniels, Dr. Ozturk, and the “many oncologists and other such knowledgeable pain specialists” who were not influenced by the 2:1 conversion ratio—were not affected by Purdue’s allegedly false marketing representations. Compl. ¶¶ 16, 17, 19. The reaction of these other doctors undercuts any potential inference that reliance on the 2:1 relative potency ratio was automatic (or even likely or typical or common), and precludes any inference that the prescriptions of Dr. Jarvis are “materially similar” to the “total pool” of OxyContin prescriptions submitted to the government from 1996 to 2005, as required under *Snapp*, 532 F.3d at 508, and *Bledsoe*, 501 F.3d at 510-11. Accordingly, these four claims could not form the basis of any broader recovery beyond the damage associated with the four claims themselves. And, of course, as discussed above, an FCA action based on these four claims is time-barred.

The allegations concerning the Salem VAMC suffer from this same defect. Radcliffe alleges that the pharmacy director said on August 9, 1999 that he would allow the “expanded” use of OxyContin at the Salem VAMC on the basis of Purdue’s marketing representations. Compl. ¶ 26. Radcliffe further alleges that there was an increase in OxyContin prescriptions at that VAMC ten months later, from May to June and July 2000. *Id.* The Complaint concedes

there was a baseline of OxyContin prescriptions at the hospital before the August 1999 sales pitch—otherwise there would be nothing to “expand” upon. This baseline of prescriptions consists of those that would have existed anyway, absent the alleged misrepresentation; in other words, these are prescriptions that were not affected by representations about the relative potency ratio. *See id.* (alleging OxyContin purchases of \$19,807 in May 2000, which increased to \$28,249 in June and over \$30,000 in July). Because the claims for reimbursement for OxyContin from the Salem VAMC are not homogenous, and, *according to the Complaint*, significantly more than half of them would have been made absent the alleged fraud, Radcliffe must identify the actual claims for which he seeks recovery. *See Snapp*, 532 F.3d at 508; *cf. Rost*, 507 F.3d at 733; *Duxbury*, 551 F. Supp. 2d at 114-15; *Foster*, 2008 WL 4360697, at *17-*18. He has not done so.

C. At a Minimum, the Action Should Be Limited to the Six Years Preceding the Filing of Radcliffe’s Complaint

In the event the Court does not dismiss the entire Complaint under Rule 9(b), the Court must at the very least limit this action to the statutory limitations period. *See Sanders*, 2008 WL 4793577, at *4-*7. Because Radcliffe filed his Complaint on September 27, 2005, claims prior to September 27, 1999 are time-barred and should be dismissed.

II. THE COURT SHOULD DISMISS RADCLIFFE’S CLAIMS BECAUSE THEY ARE BARRED BY HIS RELEASE OF CLAIMS AGAINST PURDUE

As discussed at length in Purdue’s Motion to Dismiss Radcliffe’s Third Amended Complaint, its reply in support thereof, and its Supplemental Memorandum in Support of Summary Judgment Based on Relator’s Release of Claims, Purdue respectfully contends that Radcliffe’s claims should be barred because of his pre-complaint release of all claims against Purdue at the end of his employment. *See* Dkt. 44, 61, and 99. Purdue hereby incorporates by

reference its prior briefing on this issue and renews its request that the Court dismiss this case because it is barred by the release.^{6/}

III. THE COURT SHOULD DISMISS THE STATE CLAIMS

A. The State Claims Should Be Dismissed Under Rule 9(b)—Even If the Federal Claims Survive that Rule

Radcliffe purports to sue not just in the name of the federal government but in the name of twelve states and the District of Columbia (collectively “the states”) as well. In order to do so, Radcliffe must plead a violation of *each* state statute with the specificity required by Rule 9(b). *See, e.g., Rost*, 507 F.3d at 731 n.8. (“[T]he heightened pleading standard of Rule 9(b) generally applies to state law fraud claims brought in federal court.”); *Foster*, 2008 WL 4360697, at *21 (dismissing state FCA claims for failure to satisfy Rule 9(b)). Radcliffe’s state-law claims fail to meet even the most generous reading of Rule 9(b).

As an initial matter, Radcliffe once again fails to identify any particular provision of state law as having been violated (or, in most cases, even a relevant section of statute). The state claims should be denied for that reason alone. Assuming Radcliffe intends to invoke the state-law provisions most similar to 31 U.S.C. § 3729(a)(1) and (a)(2), he falls short of the standard already imposed by the Court for such claims. Despite the Court’s previous holding that Radcliffe must identify at least one “physician [who] was influenced to prescribe OxyContin based on Purdue’s misrepresentations, [which led to] a claim for payment by the pharmacist to the government,” Radcliffe has not identified *any such individual* or claim in *any of the states* in whose name he seeks to sue, much less characteristic examples in each state. His one, time-

^{6/} Purdue reasserts the release issue to formally apply this challenge to Radcliffe’s Fourth Amended Complaint, and to ensure the issue is preserved for purposes of interlocutory appeal under 28 U.S.C. § 1292(b), should such an appeal be necessary and should leave for such an appeal be granted. To the extent necessary, the Court should construe Purdue’s argument as to the release of claims as a motion for summary judgment.

barred example relates to a private physician who wrote prescriptions filled in West Virginia, a state Radcliffe does not name in his Complaint.^{7/}

Nor does Radcliffe allege with specificity any fraudulent representations to state officials that led to any state paying for OxyContin prescriptions that would otherwise have been rejected. He alleges generically that a Purdue “Managed Care Account Executive, and others in comparable positions with Purdue, made [false representations] to the state Medicaid officials of each state to get OxyContin on each individuals state’s Medicaid formulary.” Compl. ¶ 27. But there is none of the specific detail required by Rule 9(b) as to “the time, place, and contents of the false representations, as well as the identity of the person making the misrepresentation and what he obtained thereby.” *Harrison*, 176 F.3d at 784. Radcliffe’s bare-bones allegations leave unanswered the most basic questions of his theory of liability: Did each of the 13 states exclude OxyContin from its formulary until it was induced to include it by the alleged false representations? Which states, and when? Who, specifically, made the representations, and to whom, specifically, were they made? What was the recipient’s authority to have OxyContin prescriptions paid? For how long was the decision in place before it was reconsidered? Were prescriptions in fact written after being authorized? Were the prescriptions paid from the state treasury? Under the specific pricing available to the state at the specific time, was it actually false that OxyContin was cheaper than MS Contin, given an equianalgesic ratio “materially less” than 2:1? Was this true as to all dosage strengths, or just some? Were those specific dosage strengths approved for the formulary? Was the relevant conduct within the limitations period?

^{7/} Radcliffe’s allegations regarding his misrepresentations to a VA hospital pharmacy director in Virginia have no relevance to this discussion. First, Radcliffe does not specifically identify any prescriptions induced or paid for as a result of his false statements to the pharmacy director. Second, he does not allege any such prescriptions (from a *federal* VA facility) that would have been paid with Virginia state funds. Third, the Virginia false claims statute Radcliffe invokes did not become effective until January 2003, and it does not apply retroactively. *See infra* Part III.B.5.

Radcliffe does not come close to answering any of these questions. His failure to allege with any specificity whatsoever any facts—timely or not—supporting a violation of any of the state statutes he cites requires each of his state law claims to be dismissed under Rule 9(b).

B. The Court Should Dismiss the State Claims from this Action Because of Radcliffe’s Failure to Comply with Particular State-Law Requirements

In its motion to dismiss Radcliffe’s Third Amended Complaint, Purdue articulated clear reasons why Radcliffe could not make out claims under several of the state statutes he invokes. For example, Purdue pointed to no fewer than *four* separate reasons that Radcliffe cannot invoke the Louisiana statute alone. *See, e.g.*, Reply in Support of Motion to Dismiss [Dkt. 61], at 34 & n.38. Nevertheless, Radcliffe once again drags the same list of states into yet another round of this quixotic litigation, without curing any of the defects Purdue previously identified. The Court should relieve these states of the burden of monitoring this litigation, and relieve the other parties of the obligation of serving them with future papers.

It is impracticable to address Radcliffe’s state-law claims on the merits, even more so than his federal claims. The state statutes he cites vary widely and proscribe a varying range of conduct, and Radcliffe fails once again to cite any particular state-law provision that he believes was violated, instead citing entire state statutes—another reason his Complaint should be dismissed for insufficient specificity. *See supra* Part III.A. Nevertheless, the following defects are evident even on the face of his poorly pleaded Complaint and the other pleadings to date.

1. The Court Should Dismiss Radcliffe’s Claims under the Texas and New Hampshire Acts Because Those States Declined to Intervene

The Texas and New Hampshire statutes require dismissal if the state does not intervene in the suit at the end of the period during which it remains sealed. *See* Tex. Hum. Res. Code Ann.

§ 36.104(b);^{8/} N.H. Rev. Stat. § 167:61-c.II.e.2; *Foster*, 2008 WL 4360697, at *11 (dismissing claims under Texas statute because the 60-day period for intervention had passed without government intervening). Each state named in the Complaint, including Texas and New Hampshire, declined to intervene in Radcliffe's suit. *See* Gov't Notice of Election to Decline Intervention [Dkt. 22] at 1; Order of May 8, 2007 [Dkt. 23] (discussing the impacts of "the States . . . having declined to intervene in this action pursuant to their respective state statutes"). Radcliffe's claims under the Texas and New Hampshire statutes, therefore, must be dismissed.

2. The Remaining State Claims Must Be Dismissed Because of Radcliffe's Failure to Comply with the Procedural Requirements for Filing

Each state on whose behalf Radcliffe sues requires that putative *qui tam* relators follow very particular procedures when filing their original complaint on the state's behalf. Among other things, each state requires that the complaint and a separate disclosure statement be served on particular state officials.^{9/} Several states require such service "immediately" or on the same day the complaint is filed, while others simply specify that service should be in accordance with the state's rules of procedure.^{10/} Louisiana requires that the complaint and disclosure statement

^{8/} The Texas legislature amended the Texas statute to allow relators to proceed if the state declines intervention, but the amendment "applies only to conduct that occur[ed] on or after the effective date of this Act. Conduct that occurs before the effective date of this Act is governed by the law in effect at the time the conduct occurred, and that law is continued in effect for that purpose." 2007 Tex. Sess. Law Serv. Ch. 78 (H.B. 889 (West)). The effective date of the Act was May 4, 2007. Radcliffe expressly alleges that "[t]he time period for [Purdue's] false or fraudulent claims . . . was from 1996 through July 2005." Compl. ¶ 38. The amendment to the Texas statute therefore does not apply to this action.

^{9/} *See* Nev. Rev. Stat. § 357.015(5) (requiring same-day service by mail); D.C. Code § 2-308.15(b) (3) (same-day service by mail); Cal. Gov't. Code § 12652 (B)(3)(c)(3) (same-day service); Fla. Stat. Ann. § 68.083 (3) ("[i]mmediately" upon filing of the complaint); Mass. Gen. Laws Ann. 12 § 5C(3) (requiring service pursuant to Mass. civil rule 4(d)(3)); Del. Code Ann. tit. 6 § 1203(b)(2) (service pursuant to Rules 4 and 5 of Superior Court Civil Rules); Haw. Rev. Stat. § 661-25(b) (in accordance with the Hawaii Rules of Civil Procedure); Va. Code Ann. § 8.01-216.5(B); Tenn. Code Ann. § 71-5-183(b)(2); 740 Ill. Comp. Stat. Ann. § 175/4(b)(2).

^{10/} *See id.*

be shared with state authorities 30 days *before* the complaint is filed.^{11/} Many of the states further require that the state be the named plaintiff in the suit.^{12/}

Radcliffe does not allege that he complied with these procedures, and it is clear from the record that he did not. Notwithstanding that Radcliffe clearly intended to assert claims on behalf of the states in his original complaint (*see* Dkt. 3, at ¶ 39 (“demand[ing] judgment on behalf of the states and the District of Columbia for which [he] is asserting claims based on each such states’ false claims act”)), he did not name the states as parties until more than a year later, when he filed his First Amended Complaint [Dkt. 10]. Moreover, he never claimed to have served the states with his first complaint. He only claimed to have served them nearly two years later, on the day the suit was unsealed, when he moved for leave to file his Third Amended Complaint. *See* Third Amended Compl. and Cert. of Service [Dkt. 26-29]; *see also* Amended Certificate of Service for First Amended Compl. [Dkt. 11] (claiming service on the U.S., but not the states); Second Amended Compl. and Cert. of Service [Dkt. 15] (same). Further, Radcliffe has never alleged that he served the states with the required disclosure statements.

In short, it is apparent from the record that Radcliffe failed to satisfy the state statutes’ requirements that he name and serve the states as parties and serve them with the required disclosure statements. He never served the states with his original complaint, and did not serve them with any complaint until the lawsuit had been unsealed, almost two years after his original filing, notwithstanding that many of these states required pre-filing or immediate service. And

^{11/} *See* La. Rev. Stat. Ann. § 46:439.2A(3)(a); *see also* 46:439.2A.(2)(b) (“No *qui tam* action shall be instituted by a *qui tam* plaintiff if he fails to timely file a complaint with the secretary or the attorney general.”); 46:439.2C (making failure to comply with any procedural requirement grounds for dismissal); 46:439.1.B(1) & (2) (requiring every relator to qualify as “original source,” regardless of public disclosure, where qualifying as an original source requires pre-complaint notice to state authorities).

^{12/} *See* Mass. Gen. Laws Ann. 12 § 5C(2) (suit should be brought in the name of the commonwealth); Va. Code Ann. § 8.01-216.5(A) (same); Tenn. Code Ann. § 71-5-183(b)(1) (name of the state); Cal. Gov’t. Code § 12652(c)(1) (same); Fla. Stat. Ann. § 68.083(2) (same); Haw. Rev. Stat. § 661-25(a) (same); 740 Ill. Comp. Stat. Ann. 175/4(b)(1) (same); Del. Code Ann. tit. 6 § 1203(b)(1) (name of “the government”).

there is no allegation that he ever served the required disclosure statements. These defects require dismissal. *See, e.g., Foster*, 2008 WL 4360697, at *11 n.10 (finding dismissal of Texas FCA claims was appropriate where the state was not timely served with the required disclosure statement) (citing *United States ex rel. Pilon v. Martin Marietta Corp.*, 60 F.3d 995 (2d Cir. 1995) (holding that dismissal with prejudice is appropriate where the relator did not file complaint under seal and did not serve complaint and disclosure on the government); *White v. Apollo Group*, 241 F. Supp. 2d 710 (W.D. Tex. 2003) (dismissing an FCA claim not filed under seal and not served together with written disclosures on the government)); *cf. United States ex rel. Anderson v. ITT Indus. Corp.*, No. 1:05CV720, 2006 WL 4117030, *1 (E.D. Va. Jan. 11, 2006) (“[T]he filing and service requirements for *qui tam* claims under the False Claims Act are jurisdictional in nature and . . . Plaintiff’s failure to meet those requirements, namely his failure to serve the government in the manner prescribed by statute and his premature service upon the defendant, warrants dismissal of Plaintiff’s *qui tam* claim.”).

3. **The Court Should Dismiss the Five State-Law Claims that Were Required to Be Brought in State Court in the First Instance**

The Louisiana, Massachusetts, California, Florida, and D.C. statutes authorize *qui tam* claims on behalf of the state only in the states’ own courts.^{13/} Although nothing in these statutes appears to prevent removal to, or consolidation in, federal court, each expressly anticipates that private citizens purporting to exercise this public right of action on behalf of the state should

^{13/} *See* La. Rev. Stat. Ann. § 46:439.1A, 438.1(A) (authorizing *qui tam* suits and suits by the state to be brought in “the courts of this state”); *id.* § 46:439.2 (requiring that *qui tam* complaints have a specific caption, providing certain time limits within which the complaint and information “may be filed with the appropriate state district court,” and making the relator’s failure to comply with any requirement in the subpart ground for dismissal); Mass. Gen. Laws Ann. 12 § 5C(1) & (2) (authorizing civil actions by a *qui tam* relator in “superior court”); Cal. Gov’t. Code § 12652(c)(2) (“A complaint filed by a private person under this subdivision shall be filed in superior court . . .”); D.C. Code Ann. § 2-308.15(b)(2) (“A complaint filed by a *qui tam* plaintiff pursuant to this subsection shall be filed in the Superior Court.”); Fla. Stat. Ann. § 68.083 (2) & (3) (“Civil actions instituted under this act shall be governed by the Florida Rules of Civil Procedure The complaint shall be . . . filed in the circuit court of the Second Judicial Circuit, in and for Leon County.”).

pursue the state's remedy in the first instance in state court. In the case of Florida, the suit must be filed in a particular county.^{14/} Radcliffe did not originally file in these states' courts. He therefore is suing without authorization under state law, and these claims must be dismissed.

4. The Court Should Dismiss Radcliffe's Claims Under the Louisiana Act as Untimely

The Louisiana claim must be dismissed on the additional, independent ground that it is untimely. Under the Louisiana statute, Radcliffe was required to file a complaint and disclosure statement with Louisiana authorities within a year of when "knew or should have known of the information forming the basis of the Complaint." La. Rev. Stat. Ann. § 46:439.2A(2)(b). Radcliffe did not file within this period. Every remotely material fact cited in his Complaint occurred in 2000 or earlier. He therefore knew everything he needed to know to file this action by 2000, at the absolute latest, and yet did not file his action until September 27, 2005. His Louisiana claims are therefore time-barred.

5. The Court Should Limit the Time Period of Any Remaining State Claims

In the event any state claims survive dismissal, the Court should limit the temporal scope of such claims. In all cases but one (California), the state statutes Radcliffe invokes have limitations periods as short as, or shorter than, the six-year period in the federal statute.^{15/} Therefore the Court should limit all claims (except the claims under the California statute) to alleged violations by Purdue after September 27, 1999. *See supra* Part I.C. (discussing the application of the federal limitations period). In addition, the claims under the Nevada and

^{14/} See Fla. Stat. Ann. § 68.083(3) ("The complaint shall be . . . filed in the circuit court of the Second Judicial Circuit, in and for Leon County.").

^{15/} See Haw. Rev. Stat., § 661-24 ("six years after the false claim is discovered or by exercise of reasonable diligence should have been discovered"); Tenn. Code Ann. § 71-5-184(b)(1) (6 years from the violation); Mass. Gen. Laws Ann. 12 § 5K(1) (same); Va. Code Ann. § 8.01-216.9 (6 years from the violation); Del. Code Ann. tit. 6, § 1209(a)(1) (6 years from the violation); D.C. Code Ann. § 2-308.17(a) (6 years from the violation); 740 Ill. Comp. Stat. 175/5(b)(1) (6 years from the violation).

Florida statutes should be further limited to violations occurring before September 27, 2000, because those statutes utilized a five-year limitations period at the time Radcliffe filed his original complaint.^{16/}

Further, the Court should further limit Radcliffe's claims under the Delaware, Hawaii, and Virginia statutes because those laws were enacted within the limitations period that would otherwise apply and do not apply retroactively; therefore, Radcliffe cannot recover for any alleged violations before these statutes' effective dates. When a statute does not address retroactivity, courts follow a presumption against it. *See Landgraf v. USI Film Prods.*, 511 U.S. 244, 245 (1994). The Delaware, Hawaii, and Virginia statutes do not address retroactivity. Thus, Radcliffe cannot recover for any violations against Delaware, Hawaii, and Virginia governments prior to the effective dates of those statutes: June 30, 2000; May 26, 2000; and January 1, 2003, respectively. *See* Delaware False Claims and Reporting Act, 2000 Delaware Laws Ch. 370 (H.B. 543); 2000 Hawaii Laws Act 126 (S.B. 2115); Virginia Fraud Against Taxpayers Act, 2002 Virginia Laws Ch. 842 (S.B. 445).

IV. THE COMPLAINT SHOULD BE DISMISSED WITH PREJUDICE

The Fourth Amended Complaint should be dismissed with prejudice because it contains the same deficiencies that were identified in Purdue's motion to dismiss Radcliffe's Third Amended Complaint. "[L]eave to amend may properly be denied when the party seeking leave has repeatedly failed to cure deficiencies by amendments previously allowed and when amendment would be futile." *United States ex rel. Willard v. Humana Health Plan of Tex., Inc.*, 336 F.3d 375, 387 (5th Cir. 2003); *see also, e.g., United States ex rel. Wilson v. Kellogg Brown & Root, Inc.*, 525 F.3d 370, 373 (4th Cir. 2008) (affirming denial of leave to amend FCA

^{16/} Nev. Rev. Stat. 357.170(1) (version effective prior to July 2007 amendment) (5 years from the violation); Fla. Stat. Ann. § 68.089(1) (version in effect prior to July 2007 amendment) (5 years from the violation).

complaint); *United States ex rel. Fowler v. Caremark Rx, L.L.C.*, 496 F.3d 730, 743 (7th Cir. 2007) (affirming dismissal of relator's third amended complaint and denial of leave to amend to file fourth), *cert. denied*, 128 S. Ct. 1246 (2008); *Duxbury*, 551 F. Supp. 2d at 116 (dismissing FCA case with prejudice where relator failed to cure defects by amendment); *United States ex rel. King v. Alcon Labs., Inc.*, 232 F.R.D. 568, 573 (N.D. Tex. 2005) (same). Radcliffe has now amended his complaint four times, yet he has still failed to: (i) allege any specific violations or claims within the FCA's six-year limitations period, (ii) satisfy the particularity requirements of Rule 9(b) by adequately alleging the "claims" that are the *sine qua non* of recovery under the FCA, or (iii) identify even the basic liability provisions of the False Claims Act or the state laws he alleges Purdue violated. Radcliffe should, at this point, be presumed to have alleged all of the facts that are available to him; because those facts are insufficient to state a claim upon which relief can be granted, any amendment would be futile.

V. CONCLUSION

Purdue successfully moved to dismiss Radcliffe's Third Amended Complaint, and the Court gave Radcliffe clear guidance on what was required to satisfy his pleading obligations. After three years and five attempts at a complaint, Radcliffe has once again failed to plead the required elements of a cause of action under the False Claims Act. As the Fourth Circuit recently observed in affirming the denial of leave to amend an incurably flawed FCA action: "This misguided journey must come to an end." *Wilson*, 525 F.3d at 373. So too must Radcliffe's. For the foregoing reasons, Purdue respectfully requests that the Fourth Amended

Complaint be dismissed with prejudice. Purdue further requests all additional relief to which it is entitled, and that Court deems just and proper, including costs and fees.^{17/}

Respectfully Submitted,

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^{17/} See, e.g., Fla. Stat. Ann. § 68.086(3) (“If the [state] does not proceed with an action under this act and the defendant is the prevailing party, the court shall award the defendant reasonable attorney’s fees and costs against the person bringing the action.”).